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23 December 1981

## MEMORANDUM FOR THE RECORD

SUBJECT: Human Subject Research Panel Meeting - 15 December 1981

The Human Subject Research Panel met with the Panel representatives from the General Counsel, DDS&T, DDO and DDA being present.

STAT The Panel discussed the problems, both pro and con, related to identification of the Agency as a sponsor in human research as related to the subject of informed consent on the part of research subjects. Non-disclosure of Agency sponsorship poses no apparent legal problems, although DDO policy would require CIA disclosure in the event that drugs were involved in the research. Pending receipt of a paper by the NFAC representative as to the pros and cons of Agency disclosure of sponsorship of human research, the Panel was of the opinion that the matter of disclosure of sponsorship could best be determined on a case-by-case basis by the Director or Deputy Director, with the advice of the HSRP.

STAT as the first Agency proposal under the revised HHS guidelines, will have some influence as to how subsequent proposals may be handled. At this point, the [redacted] includes a statement in the consent form for the subject's signature to the effect that the studies described are being conducted under United States Government sponsorship, and that the subject is free to withdraw without prejudice or penalty or loss of benefits if objection exists on the part of the subject to such participation. After the Institutional Review Board has evaluated the proposal and it has been studied by the HSRP, a specific recommendation will be forwarded to the Director of Central Intelligence, including a recommendation on the disclosure issue for his action. In informal discussions, the Agency has found [redacted] to be most responsive to minor modifications in the composition of the consent form. [redacted] has also queried the general literature and the general knowledge of the researchers to determine the nature and frequency of adverse reactions which might be expected. None were reported on these fronts. A query of the Food and Drug Administration was still in progress. Institutional Review Board members were in the process of being cleared, according to the General Counsel representative.

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STAT The ORD representative reported that [redacted] had been again requested by telephone on 24 November 1981 to provide documentation as to the informed consent on his project. The Panel was of the opinion that a site visit [redacted] would be in order by a Panel representative if this consent documentation has not been received by 1 January 1982.

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The Panel discussed the Presidential Commission's recommendation in the forthcoming biennial report to the President and Congress that a Government-wide office be established to oversee human research conducted by or on behalf of the Federal Government. While the Panel is of the opinion that a satisfactory working relationship could be developed with such an office, the matter is one of continuing Agency-wide concern. Although no opposition to the recommendation has been made to the Commission on behalf of the Agency, the General Counsel is aware of this recommendation, and the Agency can deal with congressional or executive office representatives at a later point should the Commission's recommendation be adopted.

The Panel will undertake an annual review of all human subject research projects ongoing beginning 1 January 1982. The Panel discussed the general issue of the Commission's plan to conduct on-site visits of ongoing human research projects to determine the methods and functions of the Institutional Review Boards. The Panel is of the opinion that such audit-type visits by a Panel representative (perhaps in association with or coordination with the Office of the Inspector) should be considered in the future.

The Panel is in agreement that its interest in human research activities pertains to the Central Intelligence Agency only and not to other members of the Intelligence Community. Staff members of the Commission have been informed (by letter in the summer of 1980) of this position and have furthermore been informed that the new Executive Order specifically includes the Intelligence Community in the HHS guidelines.

Suggestions as to revision of the wording concerning the protection of human subjects in Agency contract forms which the Panel has developed will be forwarded to the General Counsel for further consideration. In addition, inclusion of a consent provision on certain Agency records permitting evaluation of the data for future as well as current study purposes will be prepared and forwarded to the Director of Personnel and to the General Counsel for further consideration.

The Panel will send forth a suggested statement on the subject of human research which might be considered for inclusion in the Director's Notes to all employees.

The DDS&T representative stated that the [redacted] has been reviewed by the Institutional Review Board and will be available for HSRP review. A meeting will be called shortly for this purpose.

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Chairman, HSRP